# Summary of Safety and Effectiveness

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## Cardiac Pathways Corporation
## Chilli® Cooled Ablation System

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Chilli® Cooled Ablation System
Cardiac Pathways Corporation

## 1.0 GENERAL INFORMATION

| | |
|---|---|
| **Device Generic Name:** | Cooled RF Ablation System |
| **Device Trade Name:** | Chilli® Cooled Ablation System |
| **Device Model Numbers:** | |
| 41422, 41442, 45422, 45442, 43422, 43442 | Chilli® Cooled Ablation Catheter |
| 8004* | RF Generator and Pump System |
| 2062, 2063 | EGM/RF Generator Cables |
| 2035*, 2050 | EGM Bypass Switch Boxes |
| 2048*, 2066 | RF Filter Boxes |
| 2100* | Chilli® Tubing Kit |
| 2053, 2057, 2055 | EGM/PAM Junction Box Cables |
| * as approved under P980003 | |
| **Name & Address of Sponsor:** | Cardiac Pathways Corporation<br>995 Benecia Avenue<br>Sunnyvale, CA 94086 |
| **PMA Application Number:** | P990054 |
| **Date of Panel Recommendation:** | N/A |
| **Date of Notice of Approval to the Applicant:** | _____ |

## 2.0 INDICATIONS FOR USE

The Cooled Ablation System is indicated for:

- cardiac electrophysiological mapping
- delivering diagnostic pacing stimuli
- radiofrequency ablation of mappable ventricular tachycardias attributable to ischemic heart disease or cardiomyopathy in patients who have failed drug therapy

In addition, the Chilli Catheter with Tracking is used with the Arrhythmia Mapping and Tracking System to provide catheter location information.

## 3.0 CONTRAINDICATIONS

Do not use this device in the following patients:

- patients with active systemic infection
- patients with a mechanical prosthetic heart valve through which the catheter must pass
- patients with left ventricular thrombus; or with left atrial thrombus or myxoma via the transeptal approach
- patients unable to receive heparin or an acceptable alternative to achieve adequate anticoagulation

## 4.0 WARNINGS AND PRECAUTIONS

See WARNINGS AND PRECAUTIONS in the final draft labeling (Information for Use)

## 5.0 DEVICE DESCRIPTION

The Chilli Cooled Ablation System includes the Chilli Cooled Ablation Catheter (Chilli Catheter) and the Model 8004 Radiofrequency Generator and Pump System (Model 8004 RF Generator). The Chilli Cooled Ablation System was originally cleared for market release in PMA P980003. Substantial feature changes have been added to the catheters in the system and are described below. To accommodate these changes, modified cables and switch boxes were required. No changes were made to the Model 8004 RF Generator.

## 5.1 CHILLI COOLED ABLATION CATHETER

The Chilli Catheter is a 7F, quadrapolar pacing, sensing, and RF ablation catheter. The Chilli Catheter has a distal electrode segment and a proximal handle that are connected by a torquable catheter shaft. The electrode segment houses the tip electrode, the ring electrodes, and the temperature monitoring electrode. The handle includes the electrical connector for the electrode wires, a knob used to deflect the tip, and two luer fittings used to connect the catheter to the fluid pump on the Model 8004 RF Generator and the fluid collection bag, respectively. The pullwires, electrode lead wires, and two lumens carrying cooling fluid pass through the shaft. The fluid pump on the Model 8004 RF Generator circulates cooling fluid through two lumens joined at the tip.

This product contains four features which are additions to the currently marketed device:

1. Addition of optional curve sizes and catheter segment lengths that affect the overall usable length of the catheter. These changes address variability in cardiac geometry associated with ventricular cardiomyopathy, patient size, physician preference, and transeptal versus retrograde catheter insertion techniques.
2. Addition of optional bidirectional deflection that allows deflection of the distal segment in two directions. This change addresses physician preferences for catheter handling. This change also includes the adoption of a new handle design to accommodate the bidirectional deflection feature and to improve catheter manufacturability.
3. Addition of optional ultrasound transducers in the distal electrode segment that are used with a diagnostic recording system to determine the position of the catheter relative to other catheters in the heart during the mapping and ablation procedure.

4. Addition of cables and RF switch boxes to accommodate the changes to the new handle and the addition of the electrical connections of the transducers.

**Table 5-1. Summary Table of Catheter Models and Features**

| Model # | Curve & Tracking Modifier | Description | |
|---|---|---|---|
| 41422 | A, B, BX, C, D, DX, E, F, FX | 120 cm, | unidirectional, non-tracking |
| 41442 | A, B, BX, C, D, DX, E, F, FX | 120 cm, | bidirectional, non-tracking |
| 45422 | A, B, BX, C, D, DX, E, F, FX | 110 cm, | unidirectional, non-tracking |
| 45442 | A, B, BX, C, D, DX, E, F, FX | 110 cm, | bidirectional, non-tracking |
| 43422 | A, B, BX, C, D, DX, E, F, FX | 100 cm, | unidirectional, non-tracking |
| 43442 | A, B, BX, C, D, DX, E, F, FX | 100 cm, | bidirectional, non-tracking |
| | | | |
| 41422 | AT, BT, BXT, CT, DT, DXT, ET, FT, FXT | 120 cm, | unidirectional, tracking |
| 41442 | AT, BT, BXT, CT, DT, DXT, ET, FT, FXT | 120 cm, | bidirectional, tracking |
| 45422 | AT, BT, BXT, CT, DT, DXT, ET, FT, FXT | 110 cm, | unidirectional, tracking |
| 45442 | AT, BT, BXT, CT, DT, DXT, ET, FT, FXT | 110 cm, | bidirectional, tracking |
| 43422 | AT, BT, BXT, CT, DT, DXT, ET, FT, FXT | 100 cm, | unidirectional, tracking |
| 43442 | AT, BT, BXT, CT, DT, DXT, ET, FT, FXT | 100 cm, | bidirectional, tracking |

* Curves designated BX, DX and FX contain the extended distal deflecting sections.

## 5.2 MODEL 8004 RF GENERATOR

A description of the approved device can be found in P980003.

## 5.3 EGM/RF AND EGM/PAM JUNCTION BOX CABLES

The Model 2053 cable connects Chilli catheters containing ultrasound transducers to the Model 8200 Position Acquisition Module (PAM) of the Tracking System through the Model 2061 PAM Junction Box. The Model 2055 cable connects the Model 2061 PAM Junction Box to the Model 2050 RF Generator Switch Box or Model 2066 RF Filter Box for Chilli catheters that contain ultrasound transducers.

## 5.4 MODEL 2100 CHILLI TUBING KIT

A description of the approved device can be found in P980003.

## 5.5 RF GENERATOR SWITCH BOXES

The Model 2035 RF Generator Switch Box is an approved device described in P980003.

The Model 2050 Switch Box is identical in function and operation to the current Model 2035 RF Generator Switch Box except that it has been adapted to accommodate catheter models with ultrasound transducers used for tracking. The Model 2050 RF Generator Switch Box serves as a pass–through for the electrode signals from the Chilli Catheter and provides a mechanism for the clinician to switch the routing of the electrode signals between the Model 8004 RF Generator and the EGM recording instruments. Cables connect the EGM Bypass Switch Box to the Chilli Catheter, the Model 8004 RF Generator, and the signal recording/display system. The toggle switch setting determines the routing of catheter electrodes/ signals.

## 5.6 RF FILTER BOXES

The Model 2048 RF Filter Box is an approved device described in P980003.

The Model 2066 RF Filter Box is identical in function, form, and operation to the current Model 2048 RF Filter Box except it has been adapted to accommodate the new cabling required by catheter models with ultrasound transducers used for tracking.

The Model 2066 RF Filter Box filters the 500 kHz ablation signal to allow EGM signals from the Chilli Catheter to be monitored during RF delivery. Cables connect the RF Filter Box to the Chilli Catheter, the Model 8004 RF Generator, and the signal recording/display system. The switch setting determines whether the catheter electrodes/signals are filtered.

The RF Filter Box has a switch to select either Ablate or Monitor Mode. In Monitor Mode, the EGM signals are routed to the signal recording/display system and the electrodes and thermocouple are disconnected from the Model 8004 RF Generator. Temperature information is not available in this mode. The Ablate Mode is used for RF energy delivery. It activates the battery powered RF filters and connects the thermocouple to the Model 8004 RF Generator so that tip temperature can be displayed. In Ablate Mode, the EGM signals are displayed, but with decreased fidelity in comparison to Monitor Mode.

When switched to Ablate Mode, an LED is activated to indicate adequate battery power. If the LED extinguishes while in Ablate Mode, the voltage has dropped below 5 volts, and the battery needs to be replaced. No battery power is drawn in Monitor Mode.

If battery power is lost, the RF Filter Box replicates the functions of the Switch Box.

## 6.0 ALTERNATIVE PRACTICES AND PROCEDURES

Therapeutic options in patients with recurrent sustained VT include antiarrhythmic drug therapy, electrophysiologically guided ventricular surgery, and implantable cardioverter-defibrillators (ICD).

## 7.0 MARKETING HISTORY

The Chilli Cooled Ablation System described in P990054 has not been marketed. There have been no countries from which the device has been withdrawn from marketing for any reason related to the safety or effectiveness of the device.

The Chilli Cooled Ablation System described in P980003 has been marketed in the U.S.A., Germany, The Netherlands, UK, France, Italy, Spain, Slovenia, Russia, Japan, and China. There have been no countries from which the device has been withdrawn from marketing for any reason related to the safety or effectiveness of the device.

## 8.0 ADVERSE EVENTS

See **ADVERSE EVENTS** in the final draft labeling (Information for Use).

## 9.0 SUMMARY OF PRECLINICAL STUDIES

Non-clinical bench testing and animal testing have been conducted to demonstrate the safety, reliability and performance specifications of the Chilli Cooled Ablation System. The following sections summarize the results of this testing.

### 9.1 NON–CLINICAL LABORATORY STUDIES

### 9.1.1 Bench Testing – Chilli Cooled Ablation Catheter

**Biocompatibility**

All of the biocompatibility testing applies equally to the Chilli Catheter and Chilli Catheter with Tracking. Finished, EtO sterilized devices were subjected to biocompatibility testing in accordance with the requirements of ISO 10993-1. The following test battery was performed:

- Cytotoxicity, ISO Elution, L-929 Cells, 48 Hours
- Sensitization Test in Guinea Pigs (Maximization Method); Saline extract and cottonseed oil extract
- Acute Intracutaneous Reactivity Study in Rabbits; Saline extract and cottonseed oil extract
- Acute Systemic Toxicity Study in Mice; Saline extract and cottonseed oil extract
- Material Mediated Pyrogen Study in Rabbits
- Hemolysis (ASTM) in Rabbit Blood
- Complement Activation in Normal Human Serum
- Plasma Recalcification Time Coagulation

Because of the substantial anticoagulation therapy normally administered to patients undergoing ablation (i.e., increasing the clotting time by a factor of 2 to 2½) the thromboresistance testing typically performed on blood contact devices was not considered relevant. A summary of the results is presented in Table 9-1.1.a. below:

**Table 9-1.1.a. Catheter Biocompatibility Testing**

| Study | Findings |
|---|---|
| Cytotoxicity, ISO Elution, L-929 Cells, 48 Hours | Under the conditions of this study, the MEM test extracts showed no evidence of causing cell lysis or toxicity. The MEM test extracts were not cytotoxic and met the requirements of the test. The negative controls, reagent controls, and the positive controls performed as anticipated. |
| Sensitization Test in Guinea Pigs (Maximization Method); Saline extract and cottonseed oil extract | Under the conditions of this study, the SC and CSO test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig. |
| Acute Intracutaneous Reactivity Study in Rabbits; Saline extract and cottonseed oil extract | Under the conditions of this study, there was no evidence of irritation or toxicity from the extracts injected intracutaneously into rabbits. The Primary Irritation Index Characterization for the extracts was negligible. |
| Acute Systemic Toxicity Study in Mice; Saline extract and cottonseed oil extract | Under the conditions of this study, there was no mortality or evidence of systemic toxicity from the extracts. Each test article extract met the test requirements. |
| Material Mediated Pyrogen Study in Rabbits | Under the conditions of this study, the total rise of rabbit temperatures during the 3 hour observation periods were within acceptable USP limits. The extract was judged as nonpyrogenic. |
| Hemolysis (ASTM) in Rabbit Blood | Under the conditions of this study, the mean hemolytic index for the test article extracts was 0%. The test article extracts were non-hemolytic. The negative and positive controls performed as anticipated. |
| Complement Activation in Normal Human Serum | Under the conditions of this assay, the test article indicated activation at 13,450 ng/ml. This was 24% of the normalized, positive control, and reference control materials performed as anticipated. The low biomaterial reference control (LDPE) indicated activation at 8,023 ng/ml or 7.5% of the normalized, positive control. |
| Plasma Recalcification Time Coagulation | The average coagulation time of the plasma after exposure to the test article was similar to the coagulation time for the negative and plasma controls. The negative and plasma controls performed as anticipated. Under the conditions of this study, it was determined that the test article had no effect on coagulation time. |

The devices met the acceptance criteria for all tests. Since the Chilli Catheters without Tracking are made using the same blood–contact materials, the Chilli Catheters without Tracking also met the acceptance criteria for all tests.

**Bench Testing: Electrical and Mechanical**

The Chilli Cooled Ablation Catheter with the largest curve (F) and tracking was subjected to a battery of electrical and mechanical tests to verify that the devices met the specifications. The results are sown below in Table 9-1.1b. The device met the specifications.

**Table 9-1.1b. Electrical and Mechanical Testing – Chilli Cooled Ablation Catheter**

| Catheter Test Performed | # of Units Tested | Acceptance Criteria | Results |
|---|---|---|---|
| Continuity Test | 21 | All wire connections must show continuity; no open circuits | 18/20 samples met criteria; 2 showing open circuits would have been rejected during production inspection |
| Resistance Test | 21 | Total resistance between electrode and connector pin ≤ 20 Ω; total resistance between K-type pins between 350-700 Ω | All samples with correct connections met criteria |
| Conductance Test | 21 | Conductance must be > 5 mSiemens in the longitudinal mode of the 2MHz resonant frequency | All tested samples met criteria |
| Dielectric Breakdown Test | 21 | With other 12 wires tied together: each ring electrode must withstand 50 V for 30 seconds and each tip electrode must withstand 450 V for 30 seconds | 14/20 Catheters met criteria; manufacturing techniques were improved |
| Catheter Label Inspection | 11 | Tracking Logo and Color labels must remain attached to handle with less than 5% delamination | Tracking Label adhesives failed to meet acceptance criteria so new material selected; Color labels passed criteria |

| Catheter Test Performed | # of Units Tested | Acceptance Criteria | Results |
|---|---|---|---|
| Dimensional and Deflection Quality Inspection | 11 | Catheters must: pass through 7F introducer, have deflection diameter 47 mm ± 2 mm when deflected 180°, have maximum tip hooking of 2 mm, have maximum gap of 8 mm, must travel smoothly, have maximum off-axis 10 mm, have deflection angle after spring-back ≥ 180°, have maximum non-return to zero angle of 20°, have maximum secondary curve and bi-directional off-axis deflection of 25 mm | While not all samples met all original criteria, samples were accepted based on evaluations and on resulting improvements to manufacturing. Nominal deflection angles will be noted in labeling. |
| Deflection Fatigue Test | 11 | Meet all electrical and deflection criteria after 150 cycles of bi-directional testing | Not all samples met performance criteria; samples were accepted based on evaluations and on resulting improvements to manufacturing. Nominal deflection angles will be noted in labeling. |
| Distal Shaft Lateral Stiffness Test | 11 | Tip must not apply more than 12 g (0.0265 lb) of force at 90° deflection when torque is applied | All tested samples met criteria |
| Stylet Insertion/Withdrawal Force Test | 11 | Insertion or withdrawal force must be ≤3 lbs and all electrical criteria must be met | All tested samples met criteria |
| Catheter Shaft to Handle Interface Flex Test | 11 | Must meet all electrical criteria after 150 flex cycles | All tested samples met criteria |
| Torque/Turns to Failure Test | 11 | Not applicable - For performance characterization only | Average torque to failure was 2.2 in-oz, minimum was 1.6 in-oz. Turns to failure ranged from 2-4. |

| Catheter Test Performed | # of Units Tested | Acceptance Criteria | Results |
|---|---|---|---|
| 5 kHz Impedance Test | 10 | Signal attenuation must not exceed 0.5% | All tested samples met all criteria except for a single tip attenuation signal which measured 0.64% |
| Distal Buckling Force Test* | 10 | Mean distal buckling force for the longest and shortest curves must not exceed that of the comparable marketed device | All tested samples met criteria |
| Proximal Shaft Stiffness* | 10 | Mean stiffness of the proximal shaft of the bi-directional deflectable catheter must not exceed that of the comparable marketed device | All tested samples met criteria |
| Distal Shaft Stiffness* | 10 | Mean distal soft shaft stiffness must not exceed that of the comparable marketed device | All tested samples met criteria |
| Distal Non-deflectable Tip Stiffness* | 10 | Mean stiffness of the distal non-deflectable tip must not exceed that of the comparable marketed device | All tested samples met criteria |
| Pull Wire to Distal Tip Joint Tensile Test | 10 | Peak tensile force for each pull wire must be ≥ 5 lbs | All tested samples met criteria |
| Distal Tip to Distal Braided Outer Shaft Joint Tensile Test | 10 | Peak tensile force of the joints must be ≥ 3 lbs | All tested samples met criteria |
| Outer Shaft to Proximal Inner Extrusion Joint Tensile Test | 10 | Peak tensile force of the joints must be ≥ 3 lbs | All tested samples met criteria |
| Bending Stiffness Test | 10 | N/A | Product of modulus of elasticity and moment of inertia (E•I) was 0.3 lb-in$^2$; for comparable marketed device this product was 0.5 lb-in$^2$ |
| Pull Wire to Handle Joint Tensile Test | 10 | Peak tensile force for each pull wire must be ≥ 5 lbs | All tested samples met criteria |

| Catheter Test Performed | # of Units Tested | Acceptance Criteria | Results |
|---|---|---|---|
| Proximal Shaft to Handle Joint Tensile Test | 10 | Peak tensile force of the joint must be ≥ 3 lbs | All tested samples met criteria |
| Distal Soft Outer Shaft to Proximal Outer Shaft Fused Joint Tensile Test | 10 | Peak tensile force of the fused joint must be ≥ 3 lbs | All tested samples met criteria |
| Distal Inner Extrusion to Proximal Inner Extrusion Fused Joint Tensile Test | 10 | Peak tensile force of the fused joint must be ≥ 3 lbs | All tested samples met criteria |
| Temperature Test | 10 | Temperature sensor must be capable of sensing from room temperature to 37 °C in ≤ 5 seconds with accuracy of ± 2 °C, or from 37 °C to 95 °C in ≤ 8 seconds with accuracy of ± 2 °C | All samples tested met criteria |
| Flow/Pressure | 10 | Must withstand 300 psi of air pressure without leaking, demonstrate flow of 36 ml/minute with operating pressure below 200 psi | All samples tested met criteria |
| Cooling Efficiency | 10 | Must demonstrate a decrease in temperature when fluid flows through catheter | All samples tested met criteria |
| Noise | 10 | Not applicable -<br>For performance characterization only | At baseline, 9/10 samples met design goal of < 50 μVpp; range of noise levels measured was similar to that in previous testing of comparable marketed device |
| Luer Torque Test | 10 | Minimum torque withstood by luer to handle is 8 in-lb | All samples tested met criteria |

### 9.1.2 Bench Testing – Model 8004 RF Generator

Testing was performed and is described in P980003. No additional bench testing has been performed for P990054.

### 9.1.3 Bench Testing – Cables

Electrical and mechanical tested were performed on cables of similar construction and function as those listed in this PMA. Tests were performed on three complete cable assemblies for each unique cable assembly. The cables met all acceptance criteria for dimensional inspection, engagement and separation forces, resistance, noise, flex fatigue, and pulling force.

### 9.1.4 Chilli Tubing Kit

Testing was performed and is described in P980003. No additional bench testing has been performed for P990054.

### 9.1.5 RF Generator Switch Box

Testing was performed and is described in P980003. No additional bench testing has been performed for P990054.

### 9.1.6 RF Filter Box

Testing was performed and is described in P980003. No additional bench testing has been performed for P990054.

## 9.2 ANIMAL TESTING

**Animal testing was performed in compliance with GLPs to fulfill the following objectives:**

1. To demonstrate signal recording and pacing capabilities of the catheter.
2. To determine the stimulation properties of the ultrasound transmit pulse generated by the PAM hardware.
3. To verify proper performance of the Tracking System during application of radiofrequency energy.
4. To determine *in vivo* location accuracy and variability of the Tracking System.

**Objective 1. To demonstrate signal recording and pacing capabilities of the catheter.**

| Animals | Methods | Results |
|---|---|---|
| Pig (1)<br><br>Sheep (1) | Pacing thresholds determined (pig only)<br><br>Electrogram noise calculated (pig and sheep) | Pacing thresholds: ≤ 1mA<br><br>Electrogram noise: < 20μV peak-to-peak |

**Objective 2. To determine the stimulation properties of the ultrasound transmit pulse generated by the PAM hardware.**

| Animals (N) | Methods | Results |
|---|---|---|
| Pig (1) | Apply ultrasound transmit signal directly to the distal electrode. | No stimulation produced. No injury or lesions resulting from direct application of the transmit pulse. |

**Objective 3. To verify proper performance of the Tracking System during application of radiofrequency energy.**

| Animals (N) | Methods | Results |
|---|---|---|
| Pig (1)<br>Sheep (1) | Applied RF and noted performance of Tracking System | System performed as designed: the real-time tracking window froze, displaying catheter positions just prior to RF application; message appeared indicating RF interference; real-time tracking resumed with termination of RF energy. |

**Objective 4. To determine *in vivo* location accuracy of the Tracking System.**

Location accuracy was assessed using three methods, reported individually below.

Method 1. Repositioning accuracy – ability to place lesions at the "same" site using the localization feature.

| Methods | Animals (N) | Results (mean +/- SEM) |
|---|---|---|
| Tip positioned three times at "same" site using the localization feature, and RF lesion delivered. | Pig (1) | Distances among ablation positions for sites both in the RA and LV ranged from 2.6 – 7.9 mm. |
| Pathological examination of 25 lesions delivered at 9 locations in the pig and sheep heart. | Sheep (1) | Distances among ablation positions for sites both in the RA and LV ranged from 1.6 – 3.0 mm. |

Method 2 *In vivo* beat-to-beat position variability under mechanical ventilation

| Methods | Animals (N) | Results (mean +/- SEM) |
|---|---|---|
| Tip maintained in one position (3 times at each of 4 sites). Center point of position recorded for 20 consecutive cardiac cycles. | Pig (1) | Mean error: 1.6 +/- 0.6 mm |
| | Sheep (1) | Mean error: 1.5 +/1 0.6 mm |

Method 3 *In vivo* distance measurement accuracy

| Methods | Animals (N) | Results (mean +/- SEM) |
|---|---|---|
| Tip location compared to calibrated ruler for 12 determinations. | Pig (1) | Absolute error: 0.6 +/- 0.1 mm |
| | Sheep (1) | Absolute error: 0.7 +/1 0.1 mm |

## 10.0 CLINICAL INVESTIGATIONS

No clinical investigations have been performed in addition to those described in P980003.

## 11.0 CONCLUSIONS DRAWN FROM STUDIES

The preclinical testing demonstrates that the catheter should maintain its mechanical and electrical integrity and that the patient-contacting materials should be biocompatible, under the proposed conditions of use. The animal testing established an appropriate degree of localization accuracy for the Tracking feature. The clinical data submitted under P980003 provide reasonable assurance that the Chilli Cooled Ablation System is reasonably safe and effective for the stated indications, under the proposed conditions of use.

## 12.0 PANEL RECOMMENDATION

Pursuant to the provisions of section 515(c)(2) of the Food, Drug, and Cosmetic Act (FD&C) as amended by the Safe Medical Devices Act of 1990 (SMDA 1990), this PMA application was not referred to the Circulatory System Devices Panel, an FDA advisory panel committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

## 13.0 FDA DECISION

FDA determined that the devices is reasonably safe and effective when used as indicated in the labeling. CDRH issued an approval order for the applicant's PMA, P990054, on _____.

## 14.0 APPROVAL SPECIFICATIONS

**Directions for Use:** See Final Draft Labeling (Information for Use)

**Hazards to Health from Use of the Device:** See **INDICATIONS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS,** and **ADVERSE EVENTS** in the final draft labeling (Information for Use).

**Post-approval Requirements and Restrictions:** See Approval Order

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